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SECTION 5 – 510(K) SUMMARY

SEC 1 1 2006

Submitted by:	Scion Cardio-Vascular, Inc. 14256 SW 119th Avenue Miami, FL 33186 Phone: (305) 259-8880 Fax: (305) 259-8878
Contact Person:	Suzana Otaño-Lata
Date Prepared:	October 26, 2005
Proprietary Name:	M-Bolus™ Embolic Microspheres
Common Name:	Embolic Microspheres
Classification Name:	Neurovascular Embolization Device (21 CFR § 882.5950) ProCode: HCG
Predicate Device:	Boston Scientific Corporation K032707 Contour SE™ Microspheres
Device Description:	M-BOLUS™ Embolic Microspheres are made out of a biocompatible, non-degradable and non-absorbable synthetic polymer called Polyvinyl Alcohol (PVA). The M-BOLUS™ Embolic Microspheres are precisely manufactured spheres, with a smooth and lightly porous surface with hydrophilic characteristics. The M-BOLUS™ Embolic Microspheres, which are supplied in a hydrated state (0.9% Sodium Chloride), are soft and flexible allowing them to be compressed/deformed as they travel through the lumen of a delivery catheter or the vasculature. The Scion Cardio-Vascular M-BOLUS™ Embolic Microspheres are substantially equivalent to the predicate devices.
Intended Use:	The M-Bolus™ Embolic Microspheres are intended for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors. They may be used for vascular occlusion of vessels within the neurovascular system when presurgical devascularization is desirable.
Technological	The technological characteristics of the M-Bolus™ Embolic

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Characteristics:	Microspheres are the same as the predicate devices, including design and material. The M-Bolus™ successfully completed biocompatibility testing per ISO 10993-1.
Summary of Substantial Equivalence:	The Scion Cardio-Vascular M-BOLUS™ is substantially equivalent to the currently marketed Contour SE™ Microspheres. No new issues of safety or efficacy have been raised. Scion Cardio-Vascular has provided information supporting acceptability for use and substantial equivalence per Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scion Cardio-Vascular
% Ms. Suzana Otaño-Lata
Consultant
14256 S.W. 119th Aenue
Miami, Florida 33186

DEC 1 1 2006

Re: K052509
Trade/Device Name: M-BOLUS™ Embolic Microspheres
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: October 12, 2006
Received: October 13, 2006

Dear Ms. Otaño-Lata:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052509

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K052509

Device Name: M-BOLUS™ Embolic Microspheres

Indications For Use: The M-BOLUS™ Embolic Microspheres are intended for the embolization of arteriovenous malformations (AVMs) and hypervascular tumors. They may be used for vascular occlusion of vessels within the neurovascular system when presurgical devascularization is desirable.

Prescription Use X AND/OR Over-the-Counter
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052509